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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,366	07/10/2006	Matthias Kraemer	P70978US0	5554

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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
01/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,366	KRAEMER, MATTHIAS	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. In the reply filed 9/15/08, applicant amended claims 1-13. Claims 1-13 are currently pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaldon et al. (US 6,284,141).

3. With respect to Claim 1, Shaldon discloses a blood treatment device comprising a dialysis filter having two chambers separated by a semi-permeable membrane 8. The first chamber is part of a dialysis circuit having a dialysis fluid inlet and an outlet, and the second chamber is part of an extracorporeal blood circuit having a blood inlet and outlet. See Figure 4. The system further comprises a sensor (10, 11, 12) connected to an computer 14, said computer 14 being adapted to determine the concentration of a substance in the blood, the transfer rate of the substance, and total quantity of the substance withdrawn by the membrane (Column 7, Lines 21-58 and Column 5, Lines

54-64). The analyzer unit has an admissible value range for the concentration, transfer rate, and quantity removed, such that it is configured to inform the control unit that the device is performing properly and make appropriate changes when the value is outside the desired ranges (Column 5, Lines 23-64) (see Figure 2, for example). Shaldon, however, does not explicitly state that the system comprises both an analyzer unit *and* a control unit. The computer 14 disclosed by Shaldon is configured to receive and analyze data, and control the system based on said data. The computer, therefore, functions in the same manner that a separate analyzer and controller would function. It would have been obvious to one of ordinary skill in the art at the time of invention to separate the computer of Shaldon into a separate analyzer and controller because doing so would not change the functionality of the device. See MPEP § 2144.04.

4. With respect to Claim 2, at least one sensor (12) is provided in the dialysis fluid outlet line for determining the concentration of the substance.

5. With respect to Claim 6, the transfer rate value range extends from zero to a user-defined maximum value (i.e. "limit value").

6. With respect to Claims 7 and 8, the computer 14 controls the system such that a target value (i.e. "desired dose") of the substance is withdrawn (Column 8, Lines 1-7). A time-controlled ending can be programmed, thereby allowing the treatment to take a specific amount of time to complete.

7. Claims 3-5 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaldon in view of Bosetto et al. (6,793,827).

With respect to Claims 3-5 and 10-12, Shaldon discloses the system substantially as claimed, But does not specifically disclose that a second sensor is provided in the fluid inlet line for determining the substance. Bosetto discloses a dialysis system comprising a potassium sensor downstream of the dialyzer. Optionally, the system may also comprise a potassium sensor upstream of the dialyzer (Column 7, Lines 18-22), such that the difference between the potassium concentrations upstream and downstream of the dialyzer may be more accurately measured, thereby allowing the controller to accurately determine the exact amount of a substance being transferred into or out of the blood. Specifically, the use of multiple potassium sensors allows for the treatment of uremic patients by removing excess potassium from the blood (Column 1, Lines 37-53), and maintaining blood potassium concentrations at a specific level. This method of preventing hyperkalemia and hypokalemia is well established in the art of blood treatment. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the dialysis system of Shaldon with the upstream and downstream potassium sensors of Bosetto in order to accurately remove a specific amount of potassium from the blood, thereby preventing diseases such as hyperkalemia.

Additionally, regarding claims 10-12, Shaldon discloses a plurality of sensors, including flow rate sensors and a concentration sensor. The sensors allow the computer to reduce the blood concentration at an efficient rate (i.e. lowering the blood concentration at the maximum possible transfer rate). The computer determines the concentration and flow rate of the targeted substance (see above). Once determining

these values, the computer compares the concentration to the targeted concentration value and compares the flow rate to the targeted flow rate value. Shaldon, however, does not specifically disclose a concentration sensor upstream of the dialyzer for determining the concentration upstream before the exchange. Bosetto discloses a dialyzer that has upstream and downstream potassium sensors for determining the concentration of potassium in the fluid. The controller uses the concentration readings from these sensors to determine the amount of potassium removed from the blood via the dialyzer. Based on the readings from the sensors, the desired concentration, and the desired flow rate, the controller is capable of optimizing the system parameters to remove potassium from the blood as efficiently as possible based on a series of characteristics curves (see Figure 3) (Column 6, Lines 9-57). It would have been obvious to one of ordinary skill in the art at the time of invention to use the system with multiple flow sensors of Shaldon with the multiple potassium sensors of Bosetto in order to allow for concentration and flow rate measurements at any point in the flow path. The addition of these sensors would increase the overall accuracy of the system, thereby, allowing the controller to remove the targeted substance as quickly as possible. By adding an upstream concentration sensor to the Shaldon device, it would be *fully capable* of performing the intended function.

8. With respect to Claim 13, Sheldon and Bosetto disclose the system substantially as claimed (see above). Shaldon, however, does not specifically disclose that the system comprises an input device. Bosetto further discloses an input device 32 for

inputting reference values into the dialysis system's computer. These reference values are then used in calculations related to the operation of the device (column 6, Lines 9-57). It would have been obvious to one of ordinary skill in the art at the time of invention to modify device of Shaldon with the input device of Bosetto in order to allow the user to input more information about the characteristics of the flow paths, thereby allowing for more accurate calculations and allowing the system settings to be tweaked for each individual patient (Column 6, Lines 9-26).

9. With respect to Claim 9, Sheldon and Bosetto disclose the device substantially as claimed. Bosetto further disclose that the quantity of potassium eliminated during treatment depends directly on the difference between the concentration of potassium in the blood and the concentration of potassium in the dialysis fluid (Column 1, Lines 38-64). Once the concentrations in the blood and dialysis fluid are equal, transfer across the membrane will effectively cease. Controlling a dialysis system in this manner is well known in the art. Therefore, it is obvious that the controller controls the system such that the potassium concentrations of the dialysis fluid and blood will be equal when the process is complete, thereby preventing additional potassium removal from the blood.

Response to Arguments

10. Applicant's arguments filed 9/15/08 have been fully considered but they are not persuasive.

First, applicant argues that Shaldon does not teach or suggest a controller configured to determine the concentration of a substance in blood, the flow rate of said substance, or the total volume of the substance transferred. Sheldon, however, teaches that the system comprises flow rate sensors, a concentration sensor, and a plurality of pumps that are connected to a controller. The sensor data is used to calculate efficiency of the transfer. The flow rate and concentration data may be integrated to determine the total volume removed (Column 7, Lines 35-40). By monitoring the flow rate and urea concentration in the dialysis line, Sheldon's system is controlled by the controller to maintain blood urea concentrations at a predetermined level.

Second, regarding Shaldon's failure to specifically disclose an analyzer unit, Shaldon's controller functions in an identical manner to the claimed invention. Sheldon does not disclose the specific components of the controller, but it is extremely common in the art that a controller may be capable of (1) receiving a signal from one or more sensors, (2) *analyzing the sensor data*, and (3) controlling the system based on the analyzed data. Therefore, controllers that comprise "analyzer units" are well established in the art. It is the examiner's opinion that one of ordinary skill in the art at the time of invention would have recognized that an "analyzer unit" is a common part of a modern control system, and would have utilized the controller's analyzer functions in order to allow for precise control over a system.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
7 January 2008